

5

Docket No. G-056US04CIP  
Serial No. 09/978,360Remarks

Claims 14-24 are pending in the subject application. Applicants acknowledge that claims 23 and 24 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have canceled claims 16 and 21, amended claims 14, 15, and 22, and added new claims 25-27. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed (see, for example, original claim 2, paragraphs 70-71 and paragraphs 331 and 332 of the as-filed specification). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 14, 15, 17-20 and 22-27 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicants gratefully acknowledge the Examiner's withdrawal of the objections to the specification and the previous rejections under 35 U.S.C. §§101, 112, 102(b), and 102(e). Applicants also note that the Office Action Summary page indicates that "none of [the] certified copies of the priority documents have been received." Applicants respectfully submit that no foreign priority documents need be submitted since there is no claim of foreign priority under 35 U.S.C. 119(a)-(d) or (f) in this matter (in view of the now granted Petition for an Unintentionally Delayed Claim of Priority). Accordingly, correction of this indication on the Office Action Summary page is respectfully requested.

Claim 22 is rejected under 35 U.S.C. § 112, first paragraph, as nonenabled by the subject specification. The Office Action indicates that the instant specification fails to enable a polypeptide comprising from 6-500 amino acids of SEQ ID NO: 437. Applicants respectfully submit that this recitation was a typographical error and have corrected the same via amendment of the claim. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 14 and 15 are rejected under 35 U.S.C. § 102(e) as anticipated by Homburger *et al.* (U.S. Patent No. 6,703,491). In addition, claims 14 and 15 are rejected under 35 U.S.C. § 102(b) as anticipated by Korneluk *et al.* (U.S. Patent No. 5,919,912). The Office Action states that both patents teach pharmaceutical compositions comprising the polypeptide and a carrier. Applicants respectfully assert that the Homburger *et al.* and Korneluk *et al.* patents do not anticipate the claimed

J:\GEN056.US04.CIP\Amend-Resp\Amd.2d.doc\DNB/sl

invention as the references fail to teach a polypeptide comprising from 300 to 351 consecutive amino acids of SEQ ID NO: 437 or a polypeptide comprising SEQ ID NO: 437. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(e) and 102(b) is respectfully requested.

Claims 14 and 15 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office Action appears to argue that the claims directed to polypeptides comprising between 6 and 351 consecutive amino acids are not described in the as-filed specification. Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention.

As indicated in the previous response, support for the claims presented therein could be found at paragraph 70-78 of the as filed specification. Specifically, the specification indicates (at paragraphs 70-71):

[0070] Another embodiment of the present invention is a purified or isolated polypeptide comprising at least 5 or 8 consecutive amino acids of one of the sequences of SEQ ID NOs: 406-810. In one aspect of this embodiment, the purified or isolated polypeptide comprises at least 10, 12, 15, 20, 25, 30, 35, 40, 50, 60, 75, 100, 150 or 200 consecutive amino acids of one of the sequences of SEQ ID NOs: 406-810.

[0071] In addition to the above polypeptide fragments, further preferred sub-genuses of polypeptides comprise at least 8 amino acids, wherein "at least 8" is defined as any integer between 8 and the integer representing the C-terminal amino acid of the polypeptide of the present invention including the polypeptide sequences of the sequence listing below. Further included are species of polypeptide fragments at least 8 amino acids in length, as described above, that are further specified in terms of their N-terminal and C-terminal positions. Preferred species of polypeptide fragments specified by their N-terminal and C-terminal positions include the signal peptides delineated in the sequence listing below. However, included in the present invention as individual species are all polypeptide fragments, at least 8 amino acids in length, as described above, and may be particularly specified by a N-terminal and C-terminal position. That is, every combination of a N-terminal and C-terminal

position that a fragment at least 8 contiguous amino acid residues in length could occupy, on any given amino acid sequence of the sequence listing or of the present invention is included in the present invention.

While the claims have been amended to recite fragments comprising between 300 and 351 consecutive amino acids of SEQ ID NO: 437, Applicants respectfully submit that both the previously presented claims and those now presented fully comply with the written description requirement of 35 U.S.C. § 112, first paragraph. It is well-settled that the written description requirement of 35 U.S.C. § 112, first paragraph, can be satisfied without express or explicit disclosure of a later claimed invention. *See, e.g., In re Herschler*, 591 F.2d 693, 700, 200 U.S.P.Q. 711, 717 (C.C.P.A. 1979): "The claimed subject matter need not be described *in haec verba* to satisfy the description requirement. It is not necessary that the application describe the claim limitations exactly, but only so clearly that one having ordinary skill in the pertinent art would recognize from the disclosure that appellants invented processes including those limitations." (citations omitted). *See also Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323, 56 U.S.P.Q.2d 1481, 1483 (Fed. Cir. 2000) ("In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue."). Further, the standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

In light of these standards, it is respectfully submitted that one of ordinary skill in the art would have recognized that the specification conveyed that polypeptide fragments having a length corresponding to any whole number between 8 and, in the case of SEQ ID NO: 437, 352 consecutive amino acids were in possession of the inventors at the time the application was filed. As the Patent Office may be aware, the term "integer" is defined as a member of the set of positive whole numbers (1, 2, 3, ...), negative whole numbers (-1, -2, -3 ...) and zero (see attached definition drawn from

Webster's II New Riverside University Dictionary, The Riverside Publishing Co., 1988, Boston, MA). Thus, for a polypeptide of SEQ ID NO: 437, the specification would have clearly conveyed to one skilled in the art that the inventors were in possession of polypeptides comprising any number of consecutive amino acids between 8 and 352. Applicants further submit that the specification clearly sets forth polypeptide fragments comprising at least 5 or 8 consecutive amino acids of SEQ ID NOs: 406-810 (see paragraph [0070]) and original claim 2, forming a part of the disclosure as originally filed, recites:

2. A polypeptide comprising an amino acid sequence selected from the group consisting of:
  - a) any single integer from 6 to 500 amino acids of any one of SEQ ID NOs: 406-810 or of a polypeptide encoded by a human cDNA of a deposited clone;
  - b) a signal peptide sequence of any one of SEQ ID NOs: 406-810 or encoded by a human cDNA of a deposited clone;
  - c) a mature polypeptide sequence of any one of SEQ ID NOs: 406-810 or encoded by a human cDNA of a deposited clone;
  - d) a full length polypeptide sequence of any one of SEQ ID NOs: 406-810 or encoded by a human cDNA of a deposited clone; and
  - e) a polypeptide of a) through d) further comprising a physiologically acceptable carrier.

In view of these passages, Applicants respectfully submit that the as-filed specification provides adequate written description of polypeptides comprising between 6 and 351 consecutive amino acids of SEQ ID NO: 437 or, in the case of newly presented claim 26, polypeptides comprising at least 37 consecutive amino acids of SEQ ID NO: 437. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 14-22 are rejected under 35 U.S.C. § 101 and under 35 U.S.C. § 112, first paragraph, on the grounds the claimed invention is not supported by a well-established utility and, thus, one skilled in the art would not know how to use the claimed invention. Matsuda *et al.* (*Oncogene*, 2003, 3307-3318) confirms that the polypeptide of SEQ ID NO: 437 is a transcription factor activating NF- $\kappa$ B. The NF- $\kappa$ B protein plays a pivotal role in inflammatory responses (see, *e.g.*, Matsuda *et al.*, page 3307, right column, lines 8-10). The fact that SEQ ID NO: 437 is a transcription factor is disclosed in the application as filed at paragraphs 330 to 335. Example 28 of the application as filed

(paragraph 639) further teaches methods for “assaying the proteins expressed from cDNAs or fragments thereof for anti-inflammatory activity”. Accordingly, not only does the application as filed teach the correct function of the protein of SEQ ID NO: 437 (a transcription factor), but also a method of testing its role in inflammatory responses. Thus, the application as filed teaches a credible, substantial and specific utility for the polypeptide of SEQ ID NO: 437. Accordingly, reconsideration and withdrawal of the rejections is respectfully requested.

Claims 14-16, 21, and 22 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention. The Office Action argues that 6 out of 352 amino acids does not provide a sufficient structural definition of the claimed polypeptide to meet the written description requirements. In the interest of advancing prosecution in this matter, Applicants have amended claim 14 to recite polypeptides comprising 300 out of 352 amino acids (*i.e.*, 85.5% of the full-length protein) and polypeptides comprising sequences being at least 85% identical to the full-length protein. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

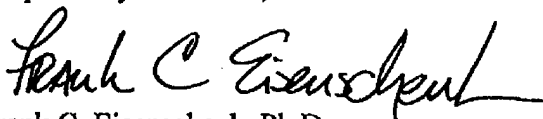
J:\GEN056\US04\CIP\Amend-Resp\Amd.2d.doc\DNB/sl

10

Docket No. G-056US04CIP  
Serial No. 09/978,360

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950  
Gainesville, FL 32614-2950

FCI/sl

Attachment: Definition of "integer" drawn from Webster's II New Riverside University  
Dictionary, The Riverside Publishing Co., 1988, Boston, MA

J:\GEN056.US04.CIP\Amend-Resp\Amnd.2d.doc\DNB/sl

S II

# New Riverside University Dictionary



The Riverside Publishing Company

BEST AVAILABLE COPY

Words that are believed to be registered trademarks have been checked with authoritative sources. No investigation has been made of common-law trademark rights in any word, because such investigation is impracticable. Words that are known to have current registrations are shown with an initial capital and are also identified as trademarks. The inclusion of any word in this Dictionary is not, however, an expression of the Publisher's opinion as to whether or not it is subject to proprietary rights. Indeed, no definition in this Dictionary is to be regarded as affecting the validity of any trademark.

Copyright © 1984, 1988 by Houghton Mifflin Company. All rights reserved.

No part of this work may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying and recording, or by any information storage or retrieval system without the prior written permission of Houghton Mifflin Company unless such copying is expressly permitted by federal copyright law. Address inquiries to Permissions, Houghton Mifflin Company, 2 Park Street, Boston, MA 02108.

Library of Congress Cataloging in Publication Data  
Main entry under title:

Webster's II new Riverside university dictionary.

I. English language—Dictionaries. I. Riverside Publishing Company. II. Title: Webster's two new Riverside university dictionary. III. Title: Webster's 2 new Riverside university dictionary.

PE1625.W244 1984 423 83-3799

ISBN: 0-395-33957-X (thumb index, trade edition)

0-395-37928-8 (high school edition)

Manufactured in the United States of America

BEST AVAILABLE COPY



## insufferable • intellect

634

**insufferable** (in-suf'ar-ə-bəl, -suf'ə-) *adj.* Incapable of being endured; INTOLERABLE <insufferable rudeness> —**insufferably** *adv.*

**insufficient** (in-sə-'fish-ənt) *adj.* Not sufficient; INADEQUATE. —**insufficiently** *adv.*

**insufflate** (in-sə-'flāt, in-suf-'flāt) *vt.* -flated, -flating, -flates. [Lat. *insufflare*, *insufflat* : Lat. *in*, on + Lat. *sufflare*, to inflate.]

1. To blow or breathe into or on. 2. To treat medically by blowing a powder, gas, or vapor into a bodily cavity. —**insufflator** *n.*

**insufflation** (in-sə-'flā-shən) *n.* 1. The act or an instance of insufflating. 2. A Christian rite of exorcism performed by breathing on a person.

**insular** (in-sə-'lār, in-sy-'lār) *adj.* [Lat. *insularis* < Lat. *insula*, island.] 1. Of, relating to, or being an island. 2. Typical or suggestive of the isolated life of an island. 3. Anatomical. Designating isolated tissue or an island of tissue. —**insularism**, **insularity** (-lār-ē-tē) *n.* —**insularly** *adv.*

**insular sclerosis** *n.* Multiple sclerosis.

**insulate** (in-sə-'lāt, in-sy-'lāt) *vt.* -lated, -lating, -lates. [Lat. *insulatus*, made into an island < Lat. *insula*, island.] 1. To cause to be in an isolated or detached position. 2. *Physics*. To prevent the passage of heat, electricity, or sound into or out of, esp. by interposition of an insulator.

**insulation** (in-sə-'lā-shən, in-sy-'lā-) *n.* 1. The act of insulating or state of being insulated. 2. Material used in insulating.

**insulator** (in-sə-'lā-tər, in-sy-'lā-) *n.* 1. An insulating material, esp. a nonconductor of heat or electricity. 2. An insulating device.

**insulin** (in-sə-'lin) *n.* [NLat. *insula*, islet (of Langerhans) < Lat. *insula* + -in.] 1. A polypeptide hormone secreted by the islets of Langerhans and functioning to regulate carbohydrate metabolism by controlling blood glucose levels. 2. A preparation derived from the pancreas of the pig or the ox for use in the medical treatment of diabetes.

**insulin shock** *n.* Hypoglycemia caused by excessive insulin in the blood.

**insult** (in-shŭlt) *v.* -sulted, -sulting, -sults. [Ofr. *insulter*, to triumph over < Lat. *insultare*, to revile : *in-*, on + *saltare*, to dance, freq. of *salire*, to jump.] —*vt.* 1. *a.* To speak to or treat insolently or contemptuously. *b.* To cause damage or offense to < a condescending remark that insulted our intelligence >. 2. *Obs.* To make an attack upon. —*vi.* *Obs.* To behave arrogantly. —*n.* (in-shŭlt') 1. An offensive action or remark. 2. *Med.* An injury, irritation, or trauma. —**insulting** *adj.* —**insultingly** *adv.*

\* **syns:** INSULT; AFFRONT; OFFEND; OUTRAGE *v.* cons meaning : to cause resentment or hurt by rude, unfeeling behavior < foul language that insulted everyone >

**insuperable** (in-sə-'pə-rə-bəl) *adj.* Incapable of being overcome; INSURMOUNTABLE <insuperable complications> —**insuperably** *adv.*

**insupportable** (in-sə-'pərt-ə-bəl, -pərt-) *adj.* 1. Unendurable; intolerable. 2. Lacking validity; UNJUSTIFIABLE <insupportable allegations> —**insupportably** *adv.*

**insuppressible** (in-sə-'prɛs-ə-bəl) *adj.* Irrepressible. —**insuppressibly** *adv.*

**insurance** (in-shŭr-əns) *n.* 1. *a.* The act, business, or system of insuring. *b.* The state of being insured. *c.* A means of being insured. 2. *a.* Contractual coverage binding a party to indemnify another against specified loss in return for premiums paid. *b.* The sum for which such a contract insures something. *c.* The premium paid for such coverage.

**insure** (in-shŭr) *v.* -sured, -suring, -sures. [ME *assuren*, to assure < Ofr. *assurer*, perh. var. of *assurer*, to assure, —see ASSURE.] —*vt.* 1. To cover with insurance. 2. To make certain or secure. —*vi.* To buy or sell insurance. —**insurable** *adj.* —**insurably** *adv.*

**insured** (in-shŭrd) *n.* One covered by insurance.

**insurer** (in-shŭr-ər) *n.* One that insures, esp. an underwriter.

**insurgence** (in-shŭr-'jən) *n.* Revolt; insurrection.

**insurgency** (in-shŭr-'jən-ē) *n.* 1. The quality or state of being insurgent. 2. Insurgence.

**insurgent** (in-shŭr-'jənt) *adj.* [Lat. *insurgens*, insurgent, pr. part. of *insurgere*, to rise up : *in-* (intensive) + *surgere*, to rise.] Rising in revolt against established authority, as a government. —*n.* 1. A person who revolts against civil authority. 2. A member of a political party who rebels against its leadership. —**insurgently** *adv.*

**insurmountable** (in-sə-'mənt-ə-bəl) *adj.* Insuperable < insurmountable difficulties > —**insurmountably** *adv.*

**insurrection** (in-sə-'rek-shən) *n.* [ME *insurrection* < Ofr. < Lat. *insurrectio* < *insurgere*, to rise up. —see INSURGENT.] An act or instance of open revolt against established authority, as a government. —**insurrectional** *adj.* —**insurrectionary** *adj.* & *n.* —**insurrectionism** *n.* —**insurrectionist** *n.*

**intact** (in-takt) *adj.* [ME *intactus* < Lat. *intactus* : *in-*, not + *tactus*, p. part. of *tangere*, to touch.] 1. Not damaged in any way. 2. Having all parts : WHOLE. —**intactness** *n.*

**intaglio** (in-tā'yō, -tā'y-) *n., pl.* -glio. [Ital. < *immaginare*, to engrave : *in-*, in < Lat. > + *tagliare*, to cut < VLat. \**tagliare* : —see TAILOR.] 1. *a.* A design or figure incised beneath the surface of hard metal or stone. *b.* The art or process of carving a design in this manner. 2. A gemstone carved in intaglio. 3. Printing done with a plate bearing an image in intaglio. 4. A die incised so as to produce a design in relief.

**intake** (in-tāk) *n.* 1. An opening by which a fluid is admitted into a container or conduit. 2. *a.* The act of taking in. *b.* Something, esp. energy, taken in.

**intangible** (in-tān-'jā-bəl) *adj.* 1. Incapable of being apprehended by the mind or senses. 2. Incapable of being defined < an intangible premonition of disaster > —*n.* Something intangible, esp. an asset that cannot be apprehended by the mind or senses. —**intangibility** *n.* —**intangibly** *adv.*

**intarsia** (in-tār-'sē-ə) *n.* [Ital. *intarsio* < *tarsia*, inlaid mosaic work < Ar. *tarṣī*.] 1. A mosaic worked in wood. 2. The art or practice of making intarsia.

**integer** (in-'tɛj-ər) *n.* [Lat. *integer*, complete.] 1. A member of the set of positive whole numbers (1, 2, 3, ...), negative whole numbers (-1, -2, -3, ...), and zero (0). 2. A complete entity or unit. —**integrable** (in-'tɛj-rə-bəl) *adj.* Capable of being integrated. —**integrability** *n.*

**integral** (in-'tɛj-rəl, in-tɛ-'grəl) *adj.* [Lat. *integrālis*, making up a whole < Lat. *integer*, complete.] 1. Essential for completeness. 2. Having everything required : ENTIRE. 3. (in-'tɛj-rəl) *Math.* *a.* Expressed or expressible as or in terms of integrals. *b.* Expressed as or involving integrals. —*n.* 1. A complete unit : WHOLE. 2. (in-'tɛj-rəl) *Math.* *a.* A definite integral. *b.* An indefinite integral. —**integrally** *adv.*

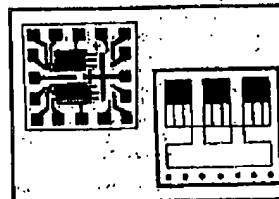
**integral calculus** *n.* The mathematical study of integration, the properties of integrals, and their applications.

**integral domain** *n.* A commutative ring with unity having no proper divisors of zero, that is, having no nonzero elements *a*, *b* such that *a**b* = 0, where 0 is the additive identity.

**integrand** (in-'tɛj-rənd) *n.* [Lat. *integranda*, gerund. of *integrare*, to integrate.] A function or equation to be integrated.

**integrate** (in-'tɛj-grət) *v.* -grated, -grating, -grates. [Lat. *integrare*, to make whole < *integer*, complete.] —*vt.* 1. To make into a whole by bringing all parts together : UNIFY. 2. To join with something else : UNITE. 3. To open without restriction to people of all races or ethnic groups : DESegREGATE. 4. *Math.* *a.* To calculate the integral of. *b.* To perform integration on. 5. To bring about the integration of (personality traits). —*vi.* To become integrated or undergo integration. —**integrative** *adj.*

**integrated circuit** *n.* A tiny wafer of substrate material on which a complex of electronic components and their interconnections is etched or imprinted. —**integrated circuitry** *n.*



Integrated circuit

**integration** (in-'tɛj-grə-'shən) *n.* 1. *a.* An act or process of integrating. *b.* The state of becoming integrated. *c.* Desegregation. 2. The organization of organic, psychological, or social traits and tendencies of a personality into a harmonious whole. —**integrative** *adj.*

**integrator** (in-'tɛj-grə-tər) *n.* 1. One that integrates. 2. An instrument for mechanically computing definite integrals.

**integrality** (in-'tɛj-grə-tē) *n.* [ME *integrates* < Ofr. < Lat. *integratio*, soundness < *integer*, whole, complete.] 1. Firm adherence to a code or standard of values : RECTITUDE. 2. The state of being unimpaired : SOUNDNESS. 3. The quality or condition of being undivided : WHOLENESS.

**integro-differential** (in-'tɛj-ə-dī-'fɛr-ən-shəl, in-tɛ-'grō-) *adj.* [INTEGRATION + DIFFERENTIAL.] Involving both mathematical differentiation and integration.

**integument** (in-'tɛj-ə-mənt) *n.* [Lat. *integumentum* < *integrare*, to cover : *in-*, on + *tegere*, to cover.] An outer covering or coat, as the skin of an animal, the coat of a seed, or the membrane enclosing an organ. —**integumentary** (-mən-'tɛ-jə, -mən-'trē) *adj.*

**intellect** (in-'tɛl-əkt) *n.* [ME < Ofr. < Lat. *intellectus*, perception < p. part. of *intelligere*, to perceive. —see INTELLIGENT.] 1. *a.* The

8 pat 4 pay 4 care 8 father 8 pot 8 be h w which 1 pte  
1 tie 1 pier 8 pot 8 toe 8 paw, for cl noise 8 toad

BEST AVAILABLE COPY